Voting Questions
Ophthalmic Devices Panel of the Medical Devices Advisory Committee

The applicant has proposed the following Indication for Use:

The KAMRA™ Inlay is indicated for the improvement of near vision in presbyopic patients who require near correction. The inlay is intended to be placed intrastromally in the cornea, on the visual axis, by way of a femtosecond laser-created pocket using a spot/line separation of 6x6 microns (µ) or less. The KAMRA™ Inlay should be placed at a depth equal to or greater than 180 µm.

The following questions relate to the approvability of the KAMRA™ Corneal Inlay, Model ACI 7000.

Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today.

Voting Question 1:

Is there reasonable assurance that the KAMRA™ Corneal Inlay, Model ACI 7000 is safe for use in patients who meet the criteria specified in the proposed indication?

Voting Question 2:

Is there reasonable assurance that the KAMRA™ Corneal Inlay, Model ACI 7000 is effective for use in the patients who meet the criteria specified in the proposed indication?

Voting Question 3:

Do the benefits of the KAMRA™ Corneal Inlay, Model ACI 7000 for use in patients who meet the criteria specified in the proposed indication outweigh the risk for use in the patients who meet the criteria specified in the proposed indication?